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| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |          |  |           |  |          |              |      |  |           |               |            |       |
|--|---------------|----------------------|--|------------------|----------|--|-----------|--|----------|--------------|------|--|-----------|---------------|------------|-------|
| 10/525,647   | 02/24/2005    | Yves Hatzfeld        | 4559-045632  | 3698             |          |  |           |  |          |              |      |  |           |               |            |       |
| 7590<br>Barbara E Johnson<br>436 Seventh Avenue<br>700 Koppers Building<br>Pittsburgh, PA 15219-1818 |               | 07/11/2007           | <table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">ZHENG, LI</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1638</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>07/11/2007</td><td>PAPER</td></tr></table> |                  | EXAMINER |  | ZHENG, LI |  | ART UNIT | PAPER NUMBER | 1638 |  | MAIL DATE | DELIVERY MODE | 07/11/2007 | PAPER |
| EXAMINER   |               |                      |  |                  |          |  |           |  |          |              |      |  |           |               |            |       |
| ZHENG, LI  |               |                      |  |                  |          |  |           |  |          |              |      |  |           |               |            |       |
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| 07/11/2007   | PAPER         |                      |  |                  |          |  |           |  |          |              |      |  |           |               |            |       |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/525,647 | <b>Applicant(s)</b><br>HATZFELD ET AL. |  |
|                              | <b>Examiner</b><br>Li Zheng          | <b>Art Unit</b><br>1638                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-25,30,31 and 36-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-25,30,31 and 36-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendment to claim 19 and cancellation of claims 26-29, 32-35 and 49 filed on 4/19/2007 are acknowledged. As a result, claims 19-25, 30-31, and 36-48 are pending and examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. All of the rejections of claims 26-29, 32-35 and 49 are withdrawn due to claim cancellation.
4. The objection to the specification is withdrawn due to specification amendment.
5. The objection to the claims 26-29, and 32-35 is withdrawn due to cancellation.
6. The rejection of claim 49 under 35 U.S.C. 112 second paragraph is withdrawn due to claim cancellation.
7. The rejection of claims 19, 21-49 under 35 U.S.C. 102(b) is withdrawn due to claim amendment.

***Claim Rejections - 35 USC § 112***

8. Claims 19-25, 30-31, and 36-48 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed November 14, 2006. Applicants traverse in the paper filed April 19, 2007 (response A) and April 26, 2007(response B). Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that claim 19 as amended does not claim dinucleotide sequences of SEQ ID NO: 18 (response, the paragraph bridging pages 8-9). However, such amendment is not enough to obviate the other issues raised in the 35 U.S.C. 112 first paragraph written description rejection.

Applicants further argue that nucleic acid variants of SEQ ID NO: 18 are described throughout the specification, for example on pages 4-7 (response, page 9, 2<sup>nd</sup> paragraph). However, those descriptions merely mention the claimed subsection without correlating a structure conserved in claimed genus to the promoter activity. The specification also fails to present representative number of species in the claimed genus. A mere mention of the claimed subject matter does not meet either prong of the two-prong test set forth by *Eli Lilly* and therefore the office concludes that Applicants are still not in possession of the claimed genus.

9. Claims 19-25, 30-31, and 36-48 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 18 being a promoter for plants, does not reasonably provide enablement for a) sequences that are at least 90% identical to SEQ ID NO: 18; b) sequences of at least 15 nucleotides in length that are specifically hybridizing under stringent condition to SEQ ID NO: 18; c) sequences of a) – b), which are interrupted by an intervening sequence; and d) sequences that are fragments of all the nucleotide sequences of a)-c), which are capable of driving expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed November 14, 2006. Applicants traverse in the paper filed April 19, 2007 (response A) and April 26, 2007 (response B). Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that claim 19 as amended does not claim dinucleotide sequences of SEQ ID NO: 18 (response A, page 9, 4<sup>th</sup> paragraph). However, such amendment is not enough to obviate other issues raised in 35 U.S.C. 112 first paragraph enablement rejection.

Applicants further argue that a complement DNA strand has promoter activity because the claimed complementary sequence embodies the information that characterizes the inventive promoter (response B, page 2, 3<sup>rd</sup> paragraph). However, the specification does not show the activity of the reverse complementary strand of SEQ ID NO: 18 and there is no evidence that SEQ ID NO: 18 is a bidirectional promoter.

***Claim Rejections - 35 USC § 103***

10. Claims 19-25, 30-31, and 36-48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. further in view of Wu et al., Padgett et al and An et al., for the reasons of record stated in the Office action mailed November 14, 2006 (note that action inadvertently listed those claims as 1-8). Applicants traverse in the paper filed April 19, 2007 (response A) and April 26, 2007 (response B). Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that Sasaki et al. do not suggest that any portion of that sequence acts as a promoter, whereas Wu et al. only disclose the mRNA of HMG1 without teaching or suggesting the promoter for the gene. Applicants further argue that even assuming that motivation to combine the references exists, additional burdensome experimentation would be required to identify the promoter for HMG1 mRNA of Wu et al. or to identify the promoter region for the sequence of Sasaki et al. (response A, page 10, 3<sup>rd</sup> paragraph). However, it is a routine practice for a person with ordinary skill in the

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art to align the mRNA to the genomic sequence to identify the gene structures including introns, exons, 5 and 3' UTRs, and putative promoter region. Such alignment can be routinely performed by various software such as BLASTN, GAP, FASTN etc. without undue experimentation.

Applicants further argue that there is no motivation to combine the references (response A, paragraph bridging pages 10-11). However, as stated in previous office action, a person with ordinary skill in the art would have been motivated to combine the references given that a DNA fragment upstream of HMGB1 coding region of Sasaki et al. is an obvious choice for promoters and the resulting expression cassette can be used for selecting Arabidopsis transformants.

### ***Summary***

No claim is allowed.

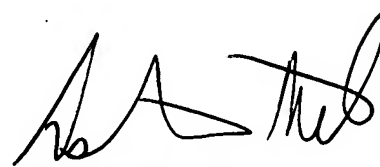
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

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The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ASHWIN D. MEHTA, PH.D.  
PRIMARY EXAMINER